

Difenoconazole  
PC Code: 128847

Dietary Exposure and Risk Assessment

DP#: 351961 and 352204



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**MEMORANDUM**

DATE: 1-MAY-2008

SUBJECT: **Difenoconazole**; Section 18 Emergency Exemption for use in/on Almond and Cucurbit Vegetables (Group 9); Acute and Chronic Dietary Exposure and Risk Assessment

PC Code: 128847  
Decision Nos: 392318 and 391843  
Petition No.: NA  
Risk Assessment: Single Chemical  
Type: Dietary  
TXR No.: NA  
MRID No.: NA

DP Barcode: 351961 and 352204  
Registration Nos: 08CA12 and 08GA01  
Regulatory Action: Section 18  
Case No.: NA  
CAS No.: 119446-68-3  
40 CFR §180.475

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TO: Mohsen Sahafeyan, Chemist  
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## **Executive Summary**

Aggregate (food + water) acute and chronic dietary exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID™, ver. 2.03) model. This model uses food consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII; 1994-1996 and 1998). The analyses were performed to support two Section 18 requests for the use of fungicide difenoconazole [1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole] in/on almond nutmeat, almond hulls, and cucurbit vegetables (group 9) with recommended time-limited tolerances at 0.05 ppm, 5.0 ppm, and 1.0 ppm, respectively.

The unrefined (Tier 1) acute and chronic analyses assumed tolerance-level residues, 100% crop treated (CT), and empirical and DEEM™ (ver. 7.81) default processing factors for most commodities. The drinking water values used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED; Memo, I. Maher, 19-JUN-2007; DP# 333319). The resulting acute and chronic aggregate exposure estimates were not of concern to HED.

### Acute Dietary (food + water) Exposure and Risk Assessment

The resulting acute food and water exposure estimates were not of concern to HED (<100% of the acute population-adjusted dose (aPAD)) at the 95<sup>th</sup> percentile of the exposure distribution for U.S. general population (2.9% aPAD) and all population subgroups; the most highly exposed population subgroup was all-infants <1 year old with 9.0% aPAD.

### Chronic Dietary (food + water) Exposure and Risk Assessment

The resulting chronic food and water exposure estimates were not of concern to HED (<100% of the chronic population-adjusted dose (cPAD)) for U.S. general population (23% cPAD) and all population sub-groups; the most highly exposed population subgroup was children 1-2 years old with 65% cPAD.

### Cancer Dietary Exposure and Risk Assessment

A cancer dietary assessment was not conducted for difenoconazole because the cancer no-observable-adverse-effect- level (NOAEL) is higher than the chronic reference dose (RfD); therefore, the chronic dietary risk estimate is protective of any cancer effects.

### Triazoles Dietary Exposure and Risk Assessments

The aggregate dietary (food + water) acute and chronic dietary exposure analyses for difenoconazole metabolites 1,2,4- triazole (1,2,4-T) and triazole alanine (TA) and triazole acetic acid (TAA) from all registered and proposed triazole-based fungicides uses already include exposure to almonds at higher-level exposures by other triazole-based fungicides and are not of concern (Memo, M. Doherty, DP#322238, 1-NOV-2005). In the case of cucurbit crop group,

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the difenoconazole residue of 1.0 ppm translates to higher exposures to triazole metabolites than from other triazole-based fungicides uses on cucurbit that are already covered in the last dietary assessment for triazoles. Although, the aggregate dietary risk assessment for triazoles are being updated to include this level of use on cucurbit, it can be said with a fairly high degree of certainty that adding these Section 18 uses will not result in any risk issues for the triazole metabolites from HED's perspective (email from M. Doherty, 5/2/08).

## I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the PAD. The PAD is equivalent to the point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf> ; or see SOP 99.6 (20-AUG-1999).

The most recent dietary risk assessment for difenoconazole was conducted by M. Sahafeyan (memo, D341303, 10/30/07).

## II. Residue Information

Difenoconazole tolerances are published in 40 CFR§180.475 (Note: The correct sugar beet tolerance is 0.3 ppm instead of 0.01 ppm; see "Notes to RD" in memorandum: M. Sahafeyan, D35175, 5/7/08)

Residues of Concern in Plants and Livestock: Table 1 below contains a summary of tolerance expression and the residues of concern in plants and livestock commodities (for details see memorandums: G. Kramer, 22-JUL-1994; No DP# and W. Wassell, DP# 340379, 8/9/07).

Table 1. Difenoconazole Residues of Concern in Plants and Ruminants.		
Matrix	Residues of Concern	
	For Risk Assessment	For Tolerance Expression
Plants	Parent Only	Parent Only
Livestock	Parent and CGA 205375	Parent and CGA 205375

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Commodities		
Milk	Parent and CGA 205375	Parent and CGA 205375
Water	Parent Only	NA

**Tolerances:** HED recommends for the establishment of Section 18 tolerances on almond nutmeat at 0.05 ppm, almond hulls at 5.0 ppm and cucurbit vegetables (crop group 9) at 1.0 ppm in response to two Section 18 requests (discussed in memorandums with DP#s: D351715 and D351302); tolerances for livestock tissues are not changed by the addition of almond hulls to their diet (M. Sahafeyan, D351715, 7-MAY-08). The established and recommended tolerances are listed in Table 2 below.

<b>Table 2. Tolerance Summary for Difenoconazole.</b>		
Commodity	Established Tolerances (ppm)	Recommended Tolerances (ppm)
Almond, nutmeat <sup>1</sup>	none	0.05
Almond, hulls <sup>1</sup>	none	5.0
Cucurbit Vegetables (Group 9)	none	1.0
Fruit, Pome, (Group 11)	1.0	-----
Vegetable, Fruiting, Group 8	0.60	-----
Vegetable, Tuberous and Corm, subgroup 1C	0.01	-----
Beet, sugar <sup>2</sup>	0.30	-----
Papaya	0.30	-----
Apple, wet pomace	4.5	-----
Beet, sugar, dried pulp	1.9	-----
Potato, processed waste	0.04	-----
Banana	0.2	-----
Barley, grain	0.1	-----
Barley, hay	0.05	-----
Barley, straw	0.05	-----
Canola, seed	0.01	-----
Cattle fat	0.10	-----
Cattle, meat	0.05	-----
Cattle, meat byproducts	0.10	-----
Cattle, liver	0.20	-----
Corn, sweet, forage	0.01	-----
Corn, sweet, kernel plus cob with husks removed	0.01	-----
Corn, sweet, stover	0.01	-----
Cotton, gin byproducts	0.05	-----
Cotton, undelinted seed	0.05	-----
Egg	0.10	-----

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Table 2. Tolerance Summary for Difenoconazole.		
Commodity	Established Tolerances (ppm)	Recommended Tolerances (ppm)
Goat, fat	0.10	-----
Goat, meat	0.05	-----
Goat, meat byproducts	0.10	-----
Goat, liver	0.20	-----
Grape	0.1	-----
Hog, fat	0.10	-----
Hog, meat	0.05	-----
Hog, meat byproducts	0.10	-----
Horse, fat	0.10	-----
Horse, meat	0.05	-----
Horse, meat byproducts	0.10	-----
Horse, liver	0.20	-----
Milk	0.01	-----
Rye, grain	0.1	-----
Sheep, fat	0.10	-----
Sheep, meat	0.05	-----
Sheep, meat byproducts	0.10	-----
Sheep, liver	0.20	-----
Wheat, forage	0.1	-----
Wheat, grain	0.1	-----
Wheat, straw	0.1	-----

<sup>1</sup> Section 18 emergency exemption tolerance.<sup>2</sup> The registered tolerance on sugar beet (0.01 ppm) needs to be changed to 0.3 ppm; see "Notes to RD" in memorandum: M. Sahafeyan, D351715, 07-MAY-08.

**Food Residues and processing factors used in the Acute and Chronic Analysis:** The acute and chronic analyses assumed tolerance-level residues for all commodities (crops and livestock tissues) and 100% CT for all the registered and proposed crops. Addition of almond hulls to the dietary burden of cattle did not result in an increase in the calculated maximum residues in beef and dairy cattle tissues. Experimental processing factors were used for apple juice (0.04x), potato chips (0.5x), potato granules/flakes (0.5x), sugar beet molasses (0.6x), sugar beet refined sugar (0.6x), tomato paste (1.6x), and tomato puree (0.5x); DEEM™ (ver. 7.81) default processing factors were assumed for other processed commodities.

### III. Drinking Water Data

The drinking water values used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED; Memo, I. Maher, 19-JUN-2007; DP# 333319). EFED conducted a Tier II drinking water assessment from surface water sources using Pesticide

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Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) model for the registered and proposed new uses and found that the highest estimated drinking water concentrations (EDWCs) are likely to be from surface water sources derived from aerial applications of difenoconazole to California ornamental nurseries at the maximum annual application rate of 0.53 lb ai/A. The estimated drinking water residues for 1-in-10 year annual peak, 1-in-10 year annual mean, and 36-year annual mean are 13.3, 9.43, and 7.18 µg/L (ppb) respectively. The second highest EDWC was from Maine potatoes.

For ground water, SCI-GROW model indicates that difenoconazole concentrations are not likely to exceed 0.00128 µg/L (ppb) from either agricultural or non-agricultural uses.

In this assessment, 1-in-10-year annual peak (13.3 ppb), and 1-in-10-year annual mean (9.43 ppb) residue values were used for acute and chronic dietary exposure assessments respectively.

#### IV. DEEM-FCID™ Program and Consumption Information

Difenoconazole acute and chronic dietary exposure assessments were conducted using the DEEM-FCID™ (ver. 2.03), which incorporates consumption data from USDA's CSFII (1994-1996 and 1998). The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (*i.e.*, apple pie) are linked to EPA-defined food commodities (*i.e.*, apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (*i.e.*, orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (*i.e.*, those who reported eating relevant commodities/food forms) and a per-capita (*i.e.*, those who reported eating the relevant

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commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for Tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

## V. Toxicological Information

Table 3 below contains a summary of the relevant toxicological information for dietary risk analyses (M. Sahafeyan, D341303, 10/30/07)

<b>Table 3. Summary of Toxicological Doses and Endpoints for Difenoconazole for Use in Dietary Risk Assessments.</b>				
<b>Exposure Scenario</b>	<b>Point of Departure</b>	<b>Uncertainty/FQPA Safety Factors</b>	<b>RfD, PAD for Risk Assessment</b>	<b>Study and Relevant Toxicological Effects</b>
Acute Dietary (All populations)	NOAEL = 25 mg/kg	UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X UF <sub>FQPA</sub> = 1X	aRfD = aPAD = 0.25 mg/kg/day	<b>Acute Neurotoxicity Study in Rats</b> LOAEL= 200 mg/kg in males based on reduced fore-limb grip strength in males on day 1.
Chronic Dietary (All populations)	NOAEL = 0.96 mg/kg/day	UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X UF <sub>FQPA</sub> = 1X	cRfD = cPAD = 0.01mg/kg/day	<b>Combined chronic toxicity/carcinogenicity (rat; dietary)</b> LOAEL = 24.1/32.8 mg/kg/day (M/F) based on cumulative decreases in body-weight gains.
Cancer (oral, dermal, inhalation)	Difenoconazole is classified as a Group C, possible human carcinogen with a non-linear (MOE) approach for human risk characterization (CPRC Document, 7/27/94, Memo, P. V. Shah dated March 3, 2007, HED Doc. No. 0054532)			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (intraspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (interspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>S</sub> = use of a short-term study for long-term risk assessment. UF<sub>DB</sub> = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure.

## VI. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the aPAD or cPAD, respectively. The following paragraphs are summaries of the DEEM-FCID™ (ver. 2.03) acute and chronic exposure analyses.

Acute and chronic aggregate (food + water) analyses were performed using DEEM-FCID™ estimating the dietary exposure of the U.S. population and various population subgroups. The results are summarized in Tables 4 and 5 below for acute and chronic analyses respectively.

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The resulting acute dietary (food + water) exposure estimates were less than HED's level of concern (<100% aPAD) at the 95<sup>th</sup> percentile of the exposure distribution for US general population (2.9% aPAD) and all population subgroups; the most highly-exposed population subgroup was all-infants <1 year old with 9.0% aPAD. The resulting chronic food exposure estimates were less than HED's level of concern (<100% cPAD) for U.S. general population (23% cPAD) and all population sub-groups; the most highly exposed population subgroup was children 1-2 years old with 65% cPAD. A cancer dietary assessment was not conducted for difenoconazole because the cancer NOAEL is higher than the chronic RfD; therefore, the chronic dietary risk estimate is more protective of any cancer effects.

**Table 4. Summary of Dietary (Food and Drinking Water) Exposure and Risk for Difenoconazole**

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary		Cancer	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD	Dietary Exposure (mg/kg/day)	Risk
General U.S. Population	0.007277	2.9	0.002265	23		
All Infants (< 1 year old)	<b>0.022518</b>	<b>9.0</b>	0.005586	56	N/A	N/A
Children 1-2 years old	0.019060	7.6	<b>0.006516</b>	<b>65</b>		
Children 3-5 years old	0.016481	6.6	0.005547	56		
Children 6-12 years old	0.009954	4.0	0.003287	33		
Youth 13-19 years old	0.004989	2.0	0.001663	17		
Adults 20-49 years old	0.004768	1.9	0.001632	16		
Adults 50+ years old	0.005685	2.3	0.001880	19		
Females 13-49 years old	0.004915	2.0	0.001637	16		

The bolded %cPAD is the highest.

## VII. Characterization of Inputs/Outputs

The acute and chronic analyses assumed tolerance-level residues, 100% CT, and empirical and DEEM™ default processing factors. Therefore, these analyses were considered conservative and could be further refined through the use of anticipated residues (ARs) for all commodities, % market share data for the proposed commodities, %CT data for registered commodities, and/or empirical processing factors for all commodities.



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## **VIII. Conclusions**

Acute and chronic aggregate (food + water) dietary risk assessments were conducted for difenoconazole using the DEEM-FCID™ (ver. 2.03) model and assumed tolerance-level residues, 100% CT, and empirical and DEEM™ default processing factors. The resulting acute and chronic aggregate exposure estimates were less than HED's level of concern, and therefore are not of concern. The most highly-exposed population subgroups in the acute (at the 95<sup>th</sup> percentile of the exposure distribution) and chronic analyses were all-infants <1 year old (9.0% aPAD) and children 1-2 years old (65% cPAD) respectively.

## **IX. Attachments**

Attachment 1: DEEM-FCID™ Acute Residue File  
Attachment 2: DEEM-FCID™ Acute Exposure Estimates  
Attachment 3: DEEM-FCID™ Chronic Residue File  
Attachment 4: DEEM-FCID™ Chronic Exposure Estimates

RDI: DESAC (23-APR-2008)  
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M. Sahafeyan: S10944:PY1:(703)-305-0776

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**Attachment 1: DEEM-FCID™ Acute Residue File**

Filename: C:\Documents and Settings\msahafey\My Documents\difenconazole\Final Documents\Section 18- almonds\difenoconazole\_acute-Sec18-043008.R98

Chemical: Difenoconazole

RfD(Chronic): .01 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day

RfD(Acute): .25 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day

Date created/last modified: 04-29-2008/10:54:48/8

Program ver. 2.03

EPA Comment Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj. Factors	
				#1	#2
14000030	14	Almond	0.050000	1.000	1.000
14000031	14	Almond-babyfood	0.050000	1.000	1.000
14000040	14	Almond, oil	0.050000	1.000	1.000
14000041	14	Almond, oil-babyfood	0.050000	1.000	1.000
11000070	11	Apple, fruit with peel	1.000000	1.000	1.000
11000080	11	Apple, peeled fruit	1.000000	1.000	1.000
11000081	11	Apple, peeled fruit-babyfood	1.000000	1.000	1.000
11000090	11	Apple, dried	1.000000	8.000	1.000
11000091	11	Apple, dried-babyfood	1.000000	8.000	1.000
11000100	11	Apple, juice	1.000000	0.040	1.000
11000101	11	Apple, juice-babyfood	1.000000	0.040	1.000
11000110	11	Apple, sauce	1.000000	1.000	1.000
11000111	11	Apple, sauce-babyfood	1.000000	1.000	1.000
09020210	9B	Balsam pear	1.000000	1.000	1.000
95000230	O	Banana	0.200000	1.000	1.000
95000231	O	Banana-babyfood	0.200000	1.000	1.000
95000240	O	Banana, dried	0.200000	3.900	1.000
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000
15000250	15	Barley, pearled barley	0.100000	1.000	1.000
15000251	15	Barley, pearled barley-babyfood	0.100000	1.000	1.000
15000260	15	Barley, flour	0.100000	1.000	1.000
15000261	15	Barley, flour-babyfood	0.100000	1.000	1.000
15000270	15	Barley, bran	0.100000	1.000	1.000
21000440	M	Beef, meat	0.050000	1.000	1.000
21000441	M	Beef, meat-babyfood	0.050000	1.000	1.000
21000450	M	Beef, meat, dried	0.050000	1.920	1.000
21000460	M	Beef, meat byproducts	0.100000	1.000	1.000
21000461	M	Beef, meat byproducts-babyfood	0.100000	1.000	1.000
21000470	M	Beef, fat	0.100000	1.000	1.000
21000471	M	Beef, fat-babyfood	0.100000	1.000	1.000
21000480	M	Beef, kidney	0.100000	1.000	1.000
21000490	M	Beef, liver	0.200000	1.000	1.000
21000491	M	Beef, liver-babyfood	0.200000	1.000	1.000
01010520	1A	Beet, sugar	0.300000	1.000	1.000
01010521	1A	Beet, sugar-babyfood	0.300000	1.000	1.000
01010530	1A	Beet, sugar, molasses	0.300000	0.600	1.000
01010531	1A	Beet, sugar, molasses-babyfood	0.300000	0.600	1.000
09010750	9A	Cantaloupe	1.000000	1.000	1.000
09010800	9A	Casaba	1.000000	1.000	1.000
09020880	9B	Chayote, fruit	1.000000	1.000	1.000
09021020	9B	Chinese waxgourd	1.000000	1.000	1.000
15001270	15	Corn, sweet	0.010000	1.000	1.000
15001271	15	Corn, sweet-babyfood	0.010000	1.000	1.000
95001280	O	Cottonseed, oil	0.050000	1.000	1.000
95001281	O	Cottonseed, oil-babyfood	0.050000	1.000	1.000
11001290	11	Crabapple	1.000000	1.000	1.000
09021350	9B	Cucumber	1.000000	1.000	1.000

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70001450	P	Egg, whole	0.100000	1.000	1.000
70001451	P	Egg, whole-babyfood	0.100000	1.000	1.000
70001460	P	Egg, white	0.100000	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.100000	1.000	1.000
70001470	P	Egg, yolk	0.100000	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.100000	1.000	1.000
23001690	M	Goat, meat	0.050000	1.000	1.000
23001700	M	Goat, meat byproducts	0.100000	1.000	1.000
23001710	M	Goat, fat	0.100000	1.000	1.000
23001720	M	Goat, kidney	0.100000	1.000	1.000
23001730	M	Goat, liver	0.200000	1.000	1.000
95001750	O	Grape	0.100000	1.000	1.000
95001760	O	Grape, juice	0.100000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.100000	1.200	1.000
95001770	O	Grape, leaves	0.100000	1.000	1.000
95001780	O	Grape, raisin	0.100000	4.300	1.000
95001790	O	Grape, wine and sherry	0.100000	1.000	1.000
09011870	9A	Honeydew melon	1.000000	1.000	1.000
24001890	M	Horse, meat	0.050000	1.000	1.000
11002100	11	Loquat	1.000000	1.000	1.000
27002220	D	Milk, fat	0.010000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.010000	1.000	1.000
27012230	D	Milk, nonfat solids	0.010000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.010000	1.000	1.000
27022240	D	Milk, water	0.010000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.010000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.010000	1.000	1.000
08002340	8	Okra	0.600000	1.000	1.000
95002450	O	Papaya	0.300000	1.000	1.000
95002451	O	Papaya-babyfood	0.300000	1.000	1.000
95002460	O	Papaya, dried	0.300000	1.800	1.000
95002470	O	Papaya, juice	0.300000	1.500	1.000
11002660	11	Pear	1.000000	1.000	1.000
11002661	11	Pear-babyfood	1.000000	1.000	1.000
11002670	11	Pear, dried	1.000000	6.250	1.000
11002680	11	Pear, juice	1.000000	1.000	1.000
11002681	11	Pear, juice-babyfood	1.000000	1.000	1.000
08002700	8	Pepper, bell	0.600000	1.000	1.000
08002701	8	Pepper, bell-babyfood	0.600000	1.000	1.000
08002710	8	Pepper, bell, dried	0.600000	1.000	1.000
08002711	8	Pepper, bell, dried-babyfood	0.600000	1.000	1.000
08002720	8	Pepper, nonbell	0.600000	1.000	1.000
08002721	8	Pepper, nonbell-babyfood	0.600000	1.000	1.000
08002730	8	Pepper, nonbell, dried	0.600000	1.000	1.000
95002830	O	Plantain	0.200000	1.000	1.000
95002840	O	Plantain, dried	0.200000	3.900	1.000
25002900	M	Pork, meat	0.050000	1.000	1.000
25002901	M	Pork, meat-babyfood	0.050000	1.000	1.000
25002910	M	Pork, skin	0.100000	1.000	1.000
25002920	M	Pork, meat byproducts	0.100000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.100000	1.000	1.000
25002930	M	Pork, fat	0.100000	1.000	1.000
25002931	M	Pork, fat-babyfood	0.100000	1.000	1.000
25002940	M	Pork, kidney	0.100000	1.000	1.000
25002950	M	Pork, liver	0.200000	1.000	1.000
01032960	1C	Potato, chips	0.010000	0.500	1.000
01032970	1C	Potato, dry (granules/ flakes)	0.010000	0.500	1.000
01032971	1C	Potato, dry (granules/ flakes)-b	0.010000	0.500	1.000
01032980	1C	Potato, flour	0.010000	1.000	1.000
01032981	1C	Potato, flour-babyfood	0.010000	1.000	1.000
01032990	1C	Potato, tuber, w/peel	0.010000	1.000	1.000
01032991	1C	Potato, tuber, w/peel-babyfood	0.010000	1.000	1.000

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01033000	1C	Potato, tuber, w/o peel	0.010000	1.000	1.000
01033001	1C	Potato, tuber, w/o peel-babyfood	0.010000	1.000	1.000
09023080	9B	Pumpkin	1.000000	1.000	1.000
09023090	9B	Pumpkin, seed	1.000000	1.000	1.000
11003100	11	Quince	1.000000	1.000	1.000
20003190	20	Rapeseed, oil	0.010000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	0.010000	1.000	1.000
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000
26003390	M	Sheep, meat	0.050000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.050000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.100000	1.000	1.000
26003410	M	Sheep, fat	0.100000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.100000	1.000	1.000
26003420	M	Sheep, kidney	0.100000	1.000	1.000
26003430	M	Sheep, liver	0.200000	1.000	1.000
09023560	9B	Squash, summer	1.000000	1.000	1.000
09023561	9B	Squash, summer-babyfood	1.000000	1.000	1.000
09023570	9B	Squash, winter	1.000000	1.000	1.000
09023571	9B	Squash, winter-babyfood	1.000000	1.000	1.000
08003740	8	Tomatillo	0.600000	1.000	1.000
08003750	8	Tomato	0.600000	1.000	1.000
08003751	8	Tomato-babyfood	0.600000	1.000	1.000
08003760	8	Tomato, paste	0.600000	1.600	1.000
08003761	8	Tomato, paste-babyfood	0.600000	1.600	1.000
08003770	8	Tomato, puree	0.600000	0.500	1.000
08003771	8	Tomato, puree-babyfood	0.600000	0.500	1.000
08003780	8	Tomato, dried	0.600000	14.300	1.000
08003781	8	Tomato, dried-babyfood	0.600000	14.300	1.000
08003790	8	Tomato, juice	0.600000	1.500	1.000
86010000	O	Water, direct, all sources	0.013300	1.000	1.000
86020000	O	Water, indirect, all sources	0.013300	1.000	1.000
09013990	9A	Watermelon	1.000000	1.000	1.000
09014000	9A	Watermelon, juice	1.000000	1.000	1.000
15004010	15	Wheat, grain	0.100000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.100000	1.000	1.000
15004020	15	Wheat, flour	0.100000	1.000	1.000
15004021	15	Wheat, flour-babyfood	0.100000	1.000	1.000
15004030	15	Wheat, germ	0.100000	1.000	1.000
15004040	15	Wheat, bran	0.100000	1.000	1.000

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**Attachment 2: DEEM-FCID™ Acute Exposure Estimates**

U.S. Environmental Protection Agency  
DEEM-FCID ACUTE Analysis for DIFENOCONAZOLE  
Residue file: difenoconazole\_acute-Sec18-043008.R98  
Adjustment factor #2 NOT used.  
Analysis Date: 04-30-2008/11:44:37      Residue file dated: 04-30-2008/11:37:24/8  
Daily totals for food and foodform consumption used.  
Run Comment: "Two section 18 requests were included: almond nutmeat (0.05 ppm)  
and cucurbit crop group 9 (1.0 ppm); livestock are not affected."  
=====

Summary calculations (per capita):

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
U.S. Population:	0.007277	2.91	0.015755	6.30	0.035323	14.13
All infants:	0.022518	9.01	0.035271	14.11	0.060480	24.19
Children 1-2 yrs:	0.019060	7.62	0.031084	12.43	0.063303	25.32
Children 3-5 yrs:	0.016481	6.59	0.029090	11.64	0.055217	22.09
Children 6-12 yrs:	0.009954	3.98	0.019901	7.96	0.043000	17.20
Youth 13-19 yrs:	0.004989	2.00	0.010215	4.09	0.027368	10.95
Adults 20-49 yrs:	0.004768	1.91	0.008419	3.37	0.018473	7.39
Adults 50+ yrs:	0.005685	2.27	0.009946	3.98	0.022200	8.88
Females 13-49 yrs:	0.004915	1.97	0.008969	3.59	0.020682	8.27

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**Attachment 3: DEEM-FCID™ Chronic Residue File**

Filename: C:\Documents and Settings\msahafey\My Documents\difenconazole\Final Documents\Section 18- almonds\difenoconazole\_chronic-Sec18-050608.R98

Chemical: Difenoconazole

RfD(Chronic): .01 mg/kg bw/day NOEL(Chronic): 4.7 mg/kg bw/day

RfD(Acute): .25 mg/kg bw/day NOEL(Acute): 25 mg/kg bw/day

Date created/last modified: 05-06-2008/12:34:16/8

Program ver. 2.03

EPA Comment Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj. Factors #1	#2
14000030	14	Almond	0.050000	1.000	1.000
14000031	14	Almond-babyfood	0.050000	1.000	1.000
14000040	14	Almond, oil	0.050000	1.000	1.000
14000041	14	Almond, oil-babyfood	0.050000	1.000	1.000
11000070	11	Apple, fruit with peel	1.000000	1.000	1.000
11000080	11	Apple, peeled fruit	1.000000	1.000	1.000
11000081	11	Apple, peeled fruit-babyfood	1.000000	1.000	1.000
11000090	11	Apple, dried	1.000000	8.000	1.000
11000091	11	Apple, dried-babyfood	1.000000	8.000	1.000
11000100	11	Apple, juice	1.000000	0.040	1.000
11000101	11	Apple, juice-babyfood	1.000000	0.040	1.000
11000110	11	Apple, sauce	1.000000	1.000	1.000
11000111	11	Apple, sauce-babyfood	1.000000	1.000	1.000
09020210	9B	Balsam pear	1.000000	1.000	1.000
95000230	O	Banana	0.200000	1.000	1.000
95000231	O	Banana-babyfood	0.200000	1.000	1.000
95000240	O	Banana, dried	0.200000	3.900	1.000
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000
15000250	15	Barley, pearled barley	0.100000	1.000	1.000
15000251	15	Barley, pearled barley-babyfood	0.100000	1.000	1.000
15000260	15	Barley, flour	0.100000	1.000	1.000
15000261	15	Barley, flour-babyfood	0.100000	1.000	1.000
15000270	15	Barley, bran	0.100000	1.000	1.000
21000440	M	Beef, meat	0.050000	1.000	1.000
21000441	M	Beef, meat-babyfood	0.050000	1.000	1.000
21000450	M	Beef, meat, dried	0.050000	1.920	1.000
21000460	M	Beef, meat byproducts	0.100000	1.000	1.000
21000461	M	Beef, meat byproducts-babyfood	0.100000	1.000	1.000
21000470	M	Beef, fat	0.100000	1.000	1.000
21000471	M	Beef, fat-babyfood	0.100000	1.000	1.000
21000480	M	Beef, kidney	0.100000	1.000	1.000
21000490	M	Beef, liver	0.200000	1.000	1.000
21000491	M	Beef, liver-babyfood	0.200000	1.000	1.000
01010520	1A	Beet, sugar	0.300000	1.000	1.000
01010521	1A	Beet, sugar-babyfood	0.300000	1.000	1.000
01010530	1A	Beet, sugar, molasses	0.300000	0.600	1.000
01010531	1A	Beet, sugar, molasses-babyfood	0.300000	0.600	1.000
09010750	9A	Cantaloupe	1.000000	1.000	1.000
09010800	9A	Casaba	1.000000	1.000	1.000
09020880	9B	Chayote, fruit	1.000000	1.000	1.000
09021020	9B	Chinese waxgourd	1.000000	1.000	1.000
15001270	15	Corn, sweet	0.010000	1.000	1.000
15001271	15	Corn, sweet-babyfood	0.010000	1.000	1.000
95001280	O	Cottonseed, oil	0.050000	1.000	1.000
95001281	O	Cottonseed, oil-babyfood	0.050000	1.000	1.000

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11001290	11	Crabapple	1.000000	1.000	1.000
09021350	9B	Cucumber	1.000000	1.000	1.000
70001450	P	Egg, whole	0.100000	1.000	1.000
70001451	P	Egg, whole-babyfood	0.100000	1.000	1.000
70001460	P	Egg, white	0.100000	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.100000	1.000	1.000
70001470	P	Egg, yolk	0.100000	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.100000	1.000	1.000
23001690	M	Goat, meat	0.050000	1.000	1.000
23001700	M	Goat, meat byproducts	0.100000	1.000	1.000
23001710	M	Goat, fat	0.100000	1.000	1.000
23001720	M	Goat, kidney	0.100000	1.000	1.000
23001730	M	Goat, liver	0.200000	1.000	1.000
95001750	O	Grape	0.100000	1.000	1.000
95001760	O	Grape, juice	0.100000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.100000	1.200	1.000
95001770	O	Grape, leaves	0.100000	1.000	1.000
95001780	O	Grape, raisin	0.100000	4.300	1.000
95001790	O	Grape, wine and sherry	0.100000	1.000	1.000
09011870	9A	Honeydew melon	1.000000	1.000	1.000
24001890	M	Horse, meat	0.050000	1.000	1.000
11002100	11	Loquat	1.000000	1.000	1.000
27002220	D	Milk, fat	0.010000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.010000	1.000	1.000
27012230	D	Milk, nonfat solids	0.010000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.010000	1.000	1.000
27022240	D	Milk, water	0.010000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.010000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.010000	1.000	1.000
08002340	8	Okra	0.600000	1.000	1.000
95002450	O	Papaya	0.300000	1.000	1.000
95002451	O	Papaya-babyfood	0.300000	1.000	1.000
95002460	O	Papaya, dried	0.300000	1.800	1.000
95002470	O	Papaya, juice	0.300000	1.500	1.000
11002660	11	Pear	1.000000	1.000	1.000
11002661	11	Pear-babyfood	1.000000	1.000	1.000
11002670	11	Pear, dried	1.000000	6.250	1.000
11002680	11	Pear, juice	1.000000	1.000	1.000
11002681	11	Pear, juice-babyfood	1.000000	1.000	1.000
08002700	8	Pepper, bell	0.600000	1.000	1.000
08002701	8	Pepper, bell-babyfood	0.600000	1.000	1.000
08002710	8	Pepper, bell, dried	0.600000	1.000	1.000
08002711	8	Pepper, bell, dried-babyfood	0.600000	1.000	1.000
08002720	8	Pepper, nonbell	0.600000	1.000	1.000
08002721	8	Pepper, nonbell-babyfood	0.600000	1.000	1.000
08002730	8	Pepper, nonbell, dried	0.600000	1.000	1.000
95002830	O	Plantain	0.200000	1.000	1.000
95002840	O	Plantain, dried	0.200000	3.900	1.000
25002900	M	Pork, meat	0.050000	1.000	1.000
25002901	M	Pork, meat-babyfood	0.050000	1.000	1.000
25002910	M	Pork, skin	0.100000	1.000	1.000
25002920	M	Pork, meat byproducts	0.100000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.100000	1.000	1.000
25002930	M	Pork, fat	0.100000	1.000	1.000
25002931	M	Pork, fat-babyfood	0.100000	1.000	1.000
25002940	M	Pork, kidney	0.100000	1.000	1.000
25002950	M	Pork, liver	0.200000	1.000	1.000
01032960	1C	Potato, chips	0.010000	0.500	1.000
01032970	1C	Potato, dry (granules/ flakes)	0.010000	0.500	1.000
01032971	1C	Potato, dry (granules/ flakes)-b	0.010000	0.500	1.000
01032980	1C	Potato, flour	0.010000	1.000	1.000
01032981	1C	Potato, flour-babyfood	0.010000	1.000	1.000

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01032990	1C	Potato, tuber, w/peel	0.010000	1.000	1.000
01032991	1C	Potato, tuber, w/peel-babyfood	0.010000	1.000	1.000
01033000	1C	Potato, tuber, w/o peel	0.010000	1.000	1.000
01033001	1C	Potato, tuber, w/o peel-babyfood	0.010000	1.000	1.000
09023080	9B	Pumpkin	1.000000	1.000	1.000
09023090	9B	Pumpkin, seed	1.000000	1.000	1.000
11003100	11	Quince	1.000000	1.000	1.000
20003190	20	Rapeseed, oil	0.010000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	0.010000	1.000	1.000
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000
26003390	M	Sheep, meat	0.050000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.050000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.100000	1.000	1.000
26003410	M	Sheep, fat	0.100000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.100000	1.000	1.000
26003420	M	Sheep, kidney	0.100000	1.000	1.000
26003430	M	Sheep, liver	0.200000	1.000	1.000
09023560	9B	Squash, summer	1.000000	1.000	1.000
09023561	9B	Squash, summer-babyfood	1.000000	1.000	1.000
09023570	9B	Squash, winter	1.000000	1.000	1.000
09023571	9B	Squash, winter-babyfood	1.000000	1.000	1.000
08003740	8	Tomatillo	0.600000	1.000	1.000
08003750	8	Tomato	0.600000	1.000	1.000
08003751	8	Tomato-babyfood	0.600000	1.000	1.000
08003760	8	Tomato, paste	0.600000	1.600	1.000
08003761	8	Tomato, paste-babyfood	0.600000	1.600	1.000
08003770	8	Tomato, puree	0.600000	0.500	1.000
08003771	8	Tomato, puree-babyfood	0.600000	0.500	1.000
08003780	8	Tomato, dried	0.600000	14.300	1.000
08003781	8	Tomato, dried-babyfood	0.600000	14.300	1.000
08003790	8	Tomato, juice	0.600000	1.500	1.000
86010000	O	Water, direct, all sources	0.009430	1.000	1.000
86020000	O	Water, indirect, all sources	0.009430	1.000	1.000
09013990	9A	Watermelon	1.000000	1.000	1.000
09014000	9A	Watermelon, juice	1.000000	1.000	1.000
15004010	15	Wheat, grain	0.100000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.100000	1.000	1.000
15004020	15	Wheat, flour	0.100000	1.000	1.000
15004021	15	Wheat, flour-babyfood	0.100000	1.000	1.000
15004030	15	Wheat, germ	0.100000	1.000	1.000
15004040	15	Wheat, bran	0.100000	1.000	1.000



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#### Attachment 4: DEEM-FCID™ Chronic Exposure Estimates

U.S. Environmental Protection Agency Ver. 2.00  
DEEM-FCID Chronic analysis for DIFENOCONAZOLE (1994-98 data)  
Residue file name: C:\Documents and Settings\msahafey\My Documents\difenconazole\Final Documents\Section 18- almonds\difenoconazole\_chronic-Sec18-050608.R98  
Adjustment factor #2 NOT used.  
Analysis Date 05-06-2008/12:35:21 Residue file dated: 05-06-2008/12:34:16/8  
Reference dose (RfD, Chronic) = .01 mg/kg bw/day

#### ----- Total exposure by population subgroup -----

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.002265	22.6%
U.S. Population (spring season)	0.002282	22.8%
U.S. Population (summer season)	0.002534	25.3%
U.S. Population (autumn season)	0.002201	22.0%
U.S. Population (winter season)	0.002030	20.3%
Northeast region	0.002352	23.5%
Midwest region	0.002285	22.8%
Southern region	0.001996	20.0%
Western region	0.002593	25.9%
Hispanics	0.002606	26.1%
Non-hispanic whites	0.002232	22.3%
Non-hispanic blacks	0.001929	19.3%
Non-hisp/non-white/non-black	0.002949	29.5%
All infants (< 1 year)	0.005586	55.9%
Nursing infants	0.003486	34.9%
Non-nursing infants	0.006383	63.8%
Children 1-6 yrs	0.005675	56.8%
Children 7-12 yrs	0.003091	30.9%
Females 13-19 (not preg or nursing)	0.001532	15.3%
Females 20+ (not preg or nursing)	0.001746	17.5%
Females 13-50 yrs	0.001819	18.2%
Females 13+ (preg/not nursing)	0.002087	20.9%
Females 13+ (nursing)	0.002461	24.6%
Males 13-19 yrs	0.001788	17.9%
Males 20+ yrs	0.001680	16.8%
Seniors 55+	0.001925	19.3%
Children 1-2 yrs	0.006516	65.2%
Children 3-5 yrs	0.005547	55.5%
Children 6-12 yrs	0.003287	32.9%
Youth 13-19 yrs	0.001663	16.6%
Adults 20-49 yrs	0.001632	16.3%
Adults 50+ yrs	0.001880	18.8%
Females 13-49 yrs	0.001637	16.4%



13544

# R159255

**Chemical Name:** Difenoconazole

**PC Code:** 128847

**HED File Code:** 11000 Chemistry Reviews

**Memo Date:** 5/1/2008

**File ID:** DPD351961

DPD352204

DPD322238

DPD351751

DPD341303

DPD340379

DPD333319

**Accession #:** 000-00-0125

**HED Records Reference Center**

7/2/2008